Agenda of the Board of Directors/NTEP Committee

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Introduction

The Board will hold their quarterly Board of Directors meeting on Saturday, January 24, 2004, and continue that meeting during work periods throughout the remainder of the Interim Meetings. Except when posted, all meetings are open to the membership. The Board of Directors and NTEP Committee will hold open hearings at the Interim Meeting and members will be invited to dialogue with the Board on issues that the Board and NTEP Committee have on their agenda. The Board of Directors is currently working on the following issues: Conformity Assessment, NCWM Organizational Structure, the National Training Program, Voting Procedures, Public Relations campaign and participation internationally, i.e., OIML, CFTM, APLMF, and U.S. NWG.

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Monday, January 26

8:30 a.m. - 5:00 p.m.

During the Board of Directors/NTEP Committee's Open Hearing, the membership is invited to provide feedback on the following issues:

1. Conformity Assessment

At the October 2003 NCWM Board Meeting, the Board discussed the current status of the NTEP Conformity Assessment Program. The Board agreed that it needs to move forward on this item and begin to formulate the details that will make up each section of the program. Steve Patoray was directed to draft a final version of NCWM Publication 14, Administrative Policy, Section S. *Conformity Assessment.* The final draft can be found in Appendix A. Explanatory information is included in Appendix B.

The Board also agreed that three work groups would be formed to complete the needed work to document the details of each of the three sections of the Program, Initial Verification, Administrative Review, and Verified Conformity Assessment Program (VCAP). Dennis Ehrhart will be identifying and contacting individuals to Chair each of these work groups.

Ross Andersen has prepared a brief presentation on Conformity Assessment Program with the intent to answer some of your questions and stimulate input from the NCWM members.

2. NCWM Organizational Structure

The Board has been examining the current Standing Committee structure. Recognizing that the members of the S & T and L & R Committees cannot be expected to be experts on all issues that come before those committees, the Board has been discussing the use of Ad Hoc Advisory Task Forces that would work on particular technical issues, reporting back to the Standing Committee.

3. National Training Program Curriculum

The Board has charged the Professional Development Committee (PDC) with developing a process to determine the curriculum for a training program. Please see the PDC agenda for the detailed description of the responsibilities that the Board has defined as the primary responsibilities of the PDC regarding the National Training Program Curriculum.

4. Voting Procedures

The Board is evaluating the current Bylaws requirements concerning the voting procedures at the annual meeting. At issue is the current requirement of 27 votes to pass or defeat an item. The Board will take comments from the membership concerning this very important issue. The BOD has discussed the concerns heard at the meeting in Sparks, NV, about the voting procedure and the corresponding number of votes required to pass or fail an item.

The Board will consider the following proposal from the Central Weights and Measures Association. It alters the number of votes required based on the number of state representatives in attendance. The intent is to provide reasonable assurance that, had the number of representatives voting been greater, the same action would have resulted. It does not alter the rules for a quorum as found in Article X, Section 5.

Proposal: Modify the NCWM Bylaws, Article X, Section 4 - Minimum Votes as follows:

Section 4 - Minimum Votes
A. House of State Representatives

When at least 35 delegates are in attendance in the House of Representatives, ~~A~~ a minimum of 27 votes in favor of, or 27 votes in opposition to, an issue must be cast for the vote to be considered official. If 54 or more votes are cast in the House of State Representatives, a simple majority of the total votes is required to pass (or defeat) the issue.

When fewer than 35 jurisdictions are in attendance in the House of Representatives, a two-thirds majority of those Representatives in attendance of the conference voting in favor of, or in opposition to, an issue must be cast for the vote to be considered official. The rules for a Quorum in still apply.

B. House of Delegates

A minimum of 27 votes in favor of, or 27 votes in opposition to, an issue must be cast for the vote to be considered official. If more than 54 total votes are cast, a simple majority rules. Should a tie vote occur, or if the minimum votes in support or opposition are not cast, the issue is decided by the vote of the House of State Representatives.

5. Public Relations Campaign

The plan for a NCWM Public Relations Campaign that was drafted by DeeAnn Deaton, Public Information Officer, Arizona Department of Weights and Measures, will be presented. Comments and suggestions will be welcomed to finalize a draft for the Annual Meeting in Pittsburgh, PA. The objectives of that plan are to:

- Increase overall awareness of the NCWM;
- Increase the total number of citizens who act as the "eyes" of weights and measures agencies;
- Increase industry compliance; and
- Increase funding support of both legislators and voters for weights and measures programs.

6. NCWM Participation in International Standards Setting Activities

Along with Craig VanBuren, incoming S&T Chairman, Dennis Ehrhart attended the Canadian Forum on Trade Measurement in Calgary, Alberta, November 19 and 20. A report will be made on the activities that took place during that meeting. Ross Andersen will also report on his participation at the APLMF meeting. Please see Appendix C for the NIST report on OIML and Appendix D for background information of the effort to harmonize U.S. weights and measures requirements with those of OIML.

Tuesday, January 27

8:30 a.m. - 12:00 noon

Board of Directors/NTEP Committee Opening Hearing

During this portion of the Board of Directors/NTEP Committee's open hearings, the Board invites the membership to an open forum where members can ask questions and provide feedback to the Board.

1:00 p.m. - 5:00 p.m.

Working session.

D. Ehrhart, Arizona, Chairman

R. Andersen, New York, Chairman of the NTEP Committee
D. Frieders, San Francisco, California, Chairman-Elect
T. Geiler, Barnstable, Massachusetts, Treasurer
M. Cleary, California
D. Onwiler, Nebraska
B. McGrath, Boston, Massachusetts
K. Angell, West Virginia
S. Pahl, Texas
C. Guay, Procter & Gamble Co.
D. Quinn, Fairbanks Scales

Executive Secretary: H. Oppermann (NIST)

Advisors: B. Palys, Executive Director, NCWM Headquarters
G. Vinet, Canada

Board of Directors

Appendix A

Publication 14, Administrative Procedures, Section S
FINAL DRAFT Nov. 6, 2003

Definition: Anytime the term manufacturer is used it refers to not only the Original Equipment Manufacturer but also to any type of re-manufacture or re-manufacturer of a device. (This will be located in the definition Section of this Publication)

S. Conformity Assessment

Type approval (certification) is one of the main elements in the metrological control system for weighing and measuring devices used in commercial measurements. The NTEP Certificate of Conformance, issued by NCWM, is a tool used by weights and measures officials in the inspection and approval of those devices. NTEP looks at one or more devices in a family, during the evaluation process. This typically occurs in the early stages of product development or production, yet it is expected that a commercial device will have a useful production life of several years. It is inevitable that changes will occur in production methods or components, that new features will be added to improve the product to respond to user needs and that the technical and performance standards will change as *NIST Handbook 44* evolves in its annual cycle. Some of these changes will result in the manufacturer requesting a reevaluation. The content and format of a Certificate of Conformance will also evolve over time.

It is vital that the Certificate of Conformance accurately reflects the device design and its features. It is also vital that the device be manufactured in conformance with the applicable requirements, while the Certificate of Conformance is in active status. In addition to the type evaluation, described in Section E. through G. of this document, the steps below outline the measures NTEP will use to keep the Certificate of Conformance accurate and to ensure conformance.

S.1 Main Elements

S.1.1 Initial Verification:

Initial Verification is the first official test of a commercial weighing and measuring device by a weights and measures official. It is another element in the metrological control system. These tests offer an invaluable means to check production devices and many, but not all, of their features against the current requirements of *NIST Handbook 44* and to verify the information provided in the NTEP Certificate of Conformance is both accurate and correct. The information gathered by the states during Initial Verification will be used to provide feedback to NTEP. NTEP will use this information to assist in the process of verifying that production devices remain in compliance and that the information on the NTEP Certificate of Conformance remains accurate.

S.1.2 Administrative Review of an NTEP Certificate of Conformance:

The Administrative Review of all NTEP Certificates of Conformance will be periodically conducted by NTEP. This review will help to ensure that:

- The NTEP Certificate of Conformance accurately reflects current Metrological Characteristics of the device as well as Standard Features and Options.

- The type remains in compliance with all current *NIST Handbook 44* requirements, including those requirements amended after the issue date of the Certificate. NTEP will consider information provided by the Certificate holder in the application and information provided by the States based on Initial Verifications.

- The NTEP Certificate of Conformance is updated periodically to provide information consistent with current practices of NTEP.

NOTE: During the phase in period NTEP will use special procedures to establish the review date for Certificates issued prior to the implementation of this Conformity Assessment policy. After this phase

in period, the Administrative Review of current active NTEP Certificate would be an ongoing process relying on feedback received from the initial verification and VCAP.

The certificate holder will be notified and shall apply to NTEP for review on or before the Review Date in a format designated by NTEP.

S.1.3 Verified Conformity Assessment Program (VCAP)

Many NTEP Certified devices must meet NIST Handbook 44 requirements for Influence Factors. It is not possible to verify these requirements during the Initial Verification in the field. Therefore, manufacturers of metrological devices (instruments) and/or components (modules) which are subject to Influence Factors, as defined in NIST Handbook 44, must have a Verified Conformity Assessment Program (VCAP) in place to ensure that these metrological devices (instruments) and/or components (modules) are produced to perform at a level consistent with that of the device and/or component previously certified. A second or third party audit must verify the Conformity Assessment Program. The second or third party must be a Certified Registrar accredited for appropriate instruments.

The Conformity Assessment Program verification will be site-specific and will focus on the site that controls the design, manufacture, quality, and testing of the device.

For weighing devices that are subject to influence factors, NTEP will require an initial on-site audit of the manufacturers' quality system and (on-site) random testing and/or review of a production device(s) (instrument(s)) by the Registrar to verify that all items listed below are currently implemented and functioning to verify compliance to the appropriate sections of NIST Handbook 44:

1. Load Cell (T.N.8.)
2. Indicating elements (T.N.8.)
3. Weighing/Load Receiving elements with non-NTEP load cells (T.N.8.)
4. Complete Scales (T.N.8.)
5. Automatic Weighing Systems (T.7.)
6. Belt-Conveyor Scales (T.3)
7. Automatic Bulk Weighing Systems (T.7.)

a. The Manufacturer has:

1. A documented Quality Management system governing the design and manufacture of the device.

2. Appropriate production and testing facilities and equipment

3. Identified the applicable Metrologically Significant Components (MSC's) of the device.

4. Appropriate statistical methods implemented to ensure that the process is in control

5. An appropriate sampling plan, and acceptance criteria in place and operating

6. Required operator's manuals and calibration procedures for all appropriate production and testing equipment

7. A Nonconforming Material system to control nonconforming / non-compliant devices and components (either manufactured or purchased).

8. Adequate control over Subcontractors and sub-tier suppliers

9. Appropriate Corrective Action system to deal with nonconforming / non-compliant devices

10. An Engineering Change system to control engineering/design changes affecting any MSC's.

11. A Document and Data Control (including software and firmware) system to control changes affecting and MSC's.

12. A Production Control system to control changes affecting any MSC's.

13. An Identification and Traceability system (including serialization and lot/batch control as applicable) applied, as a minimum, to MSC's.

14. Documentation that personnel have been properly trained.

b. If the manufacturer contracts with an outside laboratory to conduct the Influence Factor testing, that laboratory will be subject to all pertinent Conformity Assessment Program requirements.

c. A subsequent audit report provided by the Registrar, at least every five years, verifying an on-site visit to the manufacturing facility to review the statistical quality assurance and production records for all affected certified devices, and random testing or review of a production device in the manufacturing facility.

d. Information may be request from manufacturer in between the scheduled audits.

S.2 Consequences

If a Certificate holder fails to submit an application for the Administrative Review, when requested, by the review date specified, the NTEP Certificate of Conformance will become inactive.

If a Certificate holder of a device subject to influence factors fails to submit documentation, by the required date, indicating that it has and continues to maintain a Verified Conformity Assessment Program (VCAP) for influence factors, the NTEP Certificate of Conformance will become inactive.

Appendix B

Article from NCWM – NEWS, 2003
CONFORMITY ASSESSMENT: We continue on

Stephen Patoray

We have just completed a really great time at the Annual meeting. There was a lot of work done leading up to this meeting as well as a lot of comments on all types of subjects during the meeting. Most of the items up for vote passed and will become part of the respective Handbook Codes. The topic however, that was of most interest to many folks at the Conference was Conformity Assessment. There was significant discussion in the NCWM Board meetings. There were also both comments and questions from the NCWM members from the floor during the open sessions and during other times at the meeting. Some of these comments were positive and some were not. Some of the questions were very thought provoking and expressed concern over the need and intentions of certain parts of the Conformity Assessment Program or the Program as a whole. It is the intention of this article to try to answer some of these questions so that we can all move forward with the Conformity Assessment Program. Just to clarify, this article is a commentary by me on various areas of NTEP and Conformity Assessment. It is meant to be informative, and is based on my observations and thoughts as an outcome of the discussions at the Annual meeting. The NCWM Board will ultimately decide any changes to the proposed Conformity Assessment Program policy.

> I would like to start out with going back and reviewing some history. So it is clear, I am using as references for this article, several documents, both published and non-published. Some of these include the "National Conference on Weights and Measures Publication #8, Scale Manufacturers Association (SMA) "Metrology Control Plan (MCP) - 1999 rev.", several volumes of the NCWM Annual report and several non-published documents from various members of NCWM.

The United States is unique in many ways, Weights and Measures is another example of this uniqueness. Unlike most industrialized countries in the world, the United States does not have a federalized legal metrology system. The States, via the Weights and Measures Law adopted and in force in that State, govern the regulation of weighing and measuring devices used in commerce. However, like Canada, the United Kingdom, Germany, Australia and many others, we do have a similar approach to legal metrological control, these are type evaluation/certification, initial verification and subsequent verification.

The concept of pattern approval or Type Evaluation, as it is better known in the US, is not a new idea. Back in the late 1960's, the then National Bureau of Standards began issuing "Reports of Test". Also, many States had set up laboratories and required devices to be evaluated and certified before they could be placed in service within that state. In some cases, states would recognize the certificates issued by other states. In all, there were at least 15 different possible certificates that a company might be required to obtain before they could install devices in all the various states in the US. Then in the mid 1970's work began on a National Type Evaluation Program. By the mid 1980's, this program was finally adopted by the NCWM and the states began recognizing the NTEP Certificates of Conformance that were at that time issued by NIST.

"Type evaluation was put forward and has been supported by the scale industry on the basis of 3 principles: (1) to give manufacturers assurance that the engineering and operational features of a prototype device would be acceptable in advance of a hard tooling production decision; (2) to provide device manufacturers a single approval process which would be recognized by all jurisdictions; and (3) to shelter the subsequent verification subsystem from excessive failure incidents. At no time was it suggested by industry that type evaluation should assume any exceptional responsibility for or supersede the subsequent verification role in field enforcement. The initial verification function serves as the first line of defense with respect to production meeting type. Field failures further along the life cycle line can be expected to be more related to field variables than conformance to type. However, production changes relatively late in a product's life cycle can still affect performance and compliance. These events should be evident from field data failure reports." SMA MCP 1999

The concepts put forward in the SMA MCP include a Product Life Cycle. This life cycle is described as:

> "A product is conceived by a Manufacturer and is designed to the standards of the Manufacturer and within the requirements set forth by the NCWM. Once the product has reached a certain level of development, a prototype or pre-production sample of the product is submitted for type evaluation to an NTEP-assigned Testing Laboratory,

which evaluates the product to the standards developed by the NCWM. Once the product is shown to meet these requirements, the Manufacturer begins to place the product in applications, which are considered "Legal for Trade." As each unit is "placed in service" an initial verification test is performed by an official having statutory authority. From this point forward the product may experience a variety of changes or interruption in its service life. These changes involve such things as adding additional hardware with the intent of enhancing the process; to using the product for an operation which was not known when originally installed and may be performed by the end user without the original manufacturer knowledge or consent. An interruption may be the result of a product failure and may be corrected by the Manufacturer, User, or Third Party capable of performing the necessary service, but in all cases will be subjected to subsequent verification." SMA MCP 1999

I have presented this background information to show that all during the conception of NTEP, the role of type evaluation and initial verification were very closely linked. Each significant part of the product life cycle is under the control of a different responsible party. The Concept and Design phase is the responsibility of the manufacturer. The type evaluation is the responsibility of NTEP. The initial and subsequent verification is the responsibility of the State or local jurisdiction. The reporting of metrologically significant changes to the device is the responsibility of the manufacturer. And the cycle continues.

"As with any process which is intended to produce measured results, the sharing of data collected, at all stages of the process, is the key to its success. This data may be the result of testing performed by the manufacturer during the products design and initial field tests; from the laboratory testing for pattern approval (by NTEP) and both the initial and subsequent verification testing (by the States). If we look at each of the responsible parties, each one plays a major role in the checking and balancing of the process." SMA MCP 1999

I think this background provides some useful information on the role of NTEP and type evaluation. From my perspective, NTEP has proven to be a most useful tool for the States, the Consumer and the Manufacturer to ensure that a device type has the capability of meeting the requirements set forth in NIST Handbook 44. Type evaluation under NTEP also serves to provide some relief from excessive failures in the initial and subsequent verification of a device. So now, let's take a closer look at Conformity Assessment as discussed at the recent NCWM Annual meeting.

Question: Why do we need Conformity Assessment?

Answer: We need conformity assessment to ensure that devices produced after the device has been type evaluated and certified by NTEP continue to meet the same requirements.

Question: How can this be accomplished?

Answer: The States can best accomplish this for most devices and requirements through initial verification.

Question: What is initial verification?

Answer: Initial verification is conducted on a new installation of a legal for trade device by the State or local jurisdiction within the first 30 days after the device is put in service. The time is limited to the first 30 days due to the fact that during this time, the device is required to meet acceptance tolerance, after 30days maintenance tolerances are required. This verification has two parts, one is inspection and the other is performance testing.

Question: Can you explain the difference between inspection and performance testing?

Answer: The inspection portion of initial verification includes a review of the device for markings, that the NTEP CC accurately describes the features and options seen on the device being verified at this installation, that an active NTEP CC or multiple CC's cover(s) the various metrologically significant elements of the system, and that the various elements are compatible and appropriate for the installation. The performance testing is as it sounds, actually testing the device with known standards to determine that the device meets all of the performance standards of NIST HB 44.

Question: But what about influence factors, such as T.N.8. in the HB 44 scales code?

Answer: Influence factors cannot be evaluated in the field. They must be evaluated under controlled conditions.

With some of this basic knowledge, let's now discuss the three elements of the proposed Conformity Assessment Program. As they were listed in the proposed Administrative Policy, they were:

Initial verification
Administrative review
Verified Conformity Assessment Program (VCAP)

Lets go through these items one at a time. Please note that what follows are my own comments, and in some cases they may differ from what was described in the proposed policy seen in the most recent NCWM Newsletter and discussed at the July 2003 Annual meeting. This is mainly due to hearing the comments and questions at the Annual meeting. I really did attempt to listen to what was being said. All of what follows will need to be reviewed by the Work Group as they begin to work on the details and they may be changed. Also, the NCWM Board has final approval of any proposed changes to the policy.

Initial Verification

Initial verification was discussed earlier as one of the major components of the SMA Metrology Control Plan. It is key to fulfilling the need to know that subsequently produced devices are "the same" as the device that was evaluated. In simple terms, it provides surveillance. I think it is fair to say that just about everyone agrees that initial verification is the most practical and most cost effective method to attempt to understand that subsequent production devices continue to meet the same standards as the ones that were initially Certified. There were a number of very good questions on just how this would be accomplished. Some of those questions were:

What are the details of this area? How can you determine if there is a problem if you do not take into account the entire population? How will the information be collected, verified, stored, shared? Why be concerned if the problems are resolved at initial verification? Will there be training for the initial verification inspectors? Where will the time and money come from to accomplish this? These are all very good questions that need to be answered. I am not certain that I have all of the answers, but here is an attempt to answer at least some of these.

First, it is my understanding that initial verification is something that is going on in most state and local jurisdictions right now. In many jurisdictions, it is the law that a state or local inspector accomplishes this within a set period of time. There are however, significant variations in what is currently taking place in each of the various state or local jurisdictions. With the current budget shortfalls in most states, resources are being stretched. It is also very important that the data received by NTEP is good data. What could be proposed is a pilot program that focuses on one device type. States could choose to volunteer and sign up to be part of this pilot program. With this small controlled group of inspectors, the details of gathering the data, what data needs to be gathered, how the data is presented and how the data is analyzed could be worked out. From this core group, the program could then take on controlled growth into other states and other device types. These smaller steps would allow NTEP, the states and the CC holders to gain understanding and confidence in the initial verification process and its expanded role of a surveillance tool of NTEP. It would also allow for a controlled growth of the database needed to handle the potentially large amount of data. This pilot program would also allow for a review of the benefits of gathering the initial verification data. If there is no benefit shown, then Conformity Assessment could be modified. If however, the benefit shown is great, more effort and resources could be channeled in to this area to include more devices and more states. In this case, let the data tell us where we need to be going. If problems were found with certain devices, it would be a joint effort of state jurisdictions, NTEP and the CC holder to resolve those problems. The more difficult question to answer is when is there a problem? What are the trigger points? Or to put it into Statistical Process Control Language (SPC), is the process "out of control? Without a good knowledge of the field population or some way to determine a percent failure, this will be difficult. And to be honest, I do not have an answer to this issue. But I am certain that with all the great minds out there in the Conference that someone or some group will come up with an elegant solution.

Any data that is in the control of NTEP will always be treated as confidential. It would be considered part of the evaluation of the device and would not be shared with anyone other than the CC holder, unless written permission is obtained. Currently states are gathering this initial verification data. I would expect that each state handles this data a little differently.

With initial verification we still have some questions that need answers and some details to define to complete the whole process. But this is what the work group will be doing very soon. And I feel that with a pilot program we can obtain those answers and make the right decisions.

Administrative Review

I have spent a lot of time thinking about the questions and comments made at the Annual regarding the Administrative Review. I think that most of the questions can be summarized as:

Question: If you have a good initial verification program, why do you need a 10-year Administrative Review on a CC?

Answer: You probably don't.

Question: Then why do you need an Administrative Review at all?

Answer: All NTEP CC's need to be made both accurate and current.

NTEP has been issuing CC's since 1985. This has been an evolving process. Over that time, numerous people have drafted and reviewed CC's. Knowledge was gained and lost on what important information was needed on a CC. Requirements of HB 44 have changed. The criteria in Pub14 have changed. New devices and a changing list of device types have made their way on to NTEP CC's. Working with the CC's everyday as I do, I see the significant variations in the content of an NTEP CC. Quite frankly, some CC's are written much better than others. Unfortunately, there is no detailed standard for the content of an NTEP CC. A well-written CC with the correct information is vital to the success of the initial verification on a device. We need to have a standard format that CC's of each device type follows. The information should be clear, concise, and readily understood.

After rethinking this whole issue and trying to answer the question, "what are we trying to fix?" I would propose that there is still the need for an administrative review on all NTEP CC's. In keeping with the proposal for initial verification to begin with a pilot of a specific device type, I would propose that the administrative review also be started as a pilot with the same device type. With this, all CC's of the chosen device would be reviewed at the same time. They would all be brought to the same standard. Then as we move forward, any new CC would be drafted using that same standard. The updated CC's would then be a useful tool for the inspectors during initial verification. With this information, any changes or problems found during initial verification would be handled at that time. There would be no need for a review date of ten years or five years in the future. The problem would be fixed and we would move forward with a better CC and a better program. The playing field would be a bit more level.

Question: What is an Administrative review?

Answer: A review of the NTEP CC, not an evaluation of the device.

Question: Would I have to submit an actual device for testing?

Answer: NO! The only case for actual submission of a device would be if it were found that metrologically significant changes had occurred to the device since the last laboratory evaluation.

Question: Well then, what will I have to do?

Answer: The details of this will need to be worked out by the work group on this topic. But here are a few thoughts to get the conversation started.

A major item that needs completion is to have a standard set of criteria for the content of a CC for each device type. With this set of criteria a CC can be reviewed for completeness of information and formatting. Also, the CC holder and NTEP would review the CC compared to the current device's standard features and/or options, range of capacities, accuracy, applications, etc. If the NTEP CC matches up with the current device, then nothing more may need to be done in this area. The CC holder would provide current product literature to include in the current folder on this CC. Digital photos of the device might also be required for the file. The CC holder would also provide a listing of changes to the device from the time of the last NTEP evaluation due to the changes in HB 44. In many cases, the CC 's have been kept up to date. And this review would not be a great burden for either the CC holder or NTEP. The results of this review will be an accurate, clear and consistent NTEP CC. The photos and literature are a benchmark for the device. These would be in the file at NTEP and only be used to resolve issues that may arise with initial verification. These photos may or may not become a part of the NTEP CC.

Question: How much will this Administrative Review cost?

Answer: Any details relating to fee structure is a matter for the NCWM Board to approve. Any fees however, would be the responsibility of the NTEP CC holder. One possible method might be a nominal application fee to cover the basic initial CC review by NTEP staff. Then the remainder of the work would be on an hourly basis. If the NTEP CC and the information supplied by the CC holder are complete and correct, then both costs and time to NTEP would be minimal. The goal here is to keep the costs for all involved at a minimum. We must keep our eyes on the goal of having accurate, complete and consistent NTEP CC's to be used for Initial Verification.

Verified Conformity Assessment Program (VCAP)

Question: What about this Verified Conformity Assessment Program (VCAP), what is that?

Answer: The VCAP is to address the requirements in NIST HB 44 that relate to influence factors. T.N.8 from the Scales code is the section that is most familiar to people.

Question: What is so special about influence factors? I thought we were doing an initial verification on all devices.

Answer: An initial verification in the field cannot test for influence factors. These are things like performance changes over a range of temperature. Changes due to barometric pressure, and changes due to power fluctuations may also be evaluated.

Question: Why not do these in the field at initial verification?

Answer: NIST HB 44 states (2.20 Scales T.N.8. Influence Factors.) that these tests must be conducted under controlled conditions. These tests must be done in a lab.

Question: What types of devices need to meet influence factors?

Answer: Currently only Weighing Devices: Scales, load cells, indicating elements, Automatic Bulk Weighing Systems, Automatic Weighing Systems, Belt Conveyor Scales etc.

Question: So what are the CC holders of weighing devices going to have to do to meet the VCAP requirement?

Answer: In very simple terms the VCAP will require an on-site audit by a certified Registrar accredited for weighing and measuring instruments. The audit criteria are fourteen items that are taken generally from the ISO 9001-2000 guidelines for quality systems. These fourteen items follow at the end of this section in Appendix A.

Question: Why not just use the ISO certification as evidence that these devices meet type?

Answer: The requirements of ISO 9000 series are very broad in scope and while they provided evidence that a quality system is in place and that processes may be completed consistently, it does not require that devices actually meet specific performance requirements of HB 44. The requirements of VCAP are focused on only those aspects of the manufacturing process related to meeting the influence factors for weighing devices as described in NIST HB 44.

Question: So this is an audit in addition to any current ISO auditing?

Answer: Yes

The VCAP will be site specific and will focus on the site that controls the design, manufacture, quality and testing of the Certified device.

Question: What do you mean by site specific?

Answer: Site specific is a term used by VCAP to refer to one actual site, whether that be a manufacturing facility or a laboratory, which controls the various aspects related to influence factors for a single device or for many devices. An example is a load cell manufacturer. The manufacturer may hold many NTEP CC's on many types of load cells. However, all of the load cells are manufactured, tested and compensated at one manufacturing facility or site. This one site controls the various aspects of all of the Certified devices. Only this one site would need to be audited and certified,

to cover all of the various Certified devices. This is different from another manufacturer who may manufacture devices or different types in various manufacturing facilities; let's just say aluminum single point load cells at one facility and stainless steel double end shear beams in another facility in another part of the country. Each of the different sites that control the various aspects of that particular certified device would need to be audited and certified for the respective Certified devices that they have control over.

Question: What if I have a separate laboratory conducting audits on production samples?

Answer: This laboratory would be a part of an overall documented Quality Management System governing design and manufacture of the Certified Device. As such, it would need to be audited and certified for the applicable requirements for the functions of the lab. Other requirements would need to be audited and certified at the site that actually controls these particular aspects of the Certified device.

The simple answer here is that each company operates their business as best they can. There are differences in philosophies, size, number of devices, and many other factors that come into play. It is the intent of the VCAP program to verify that there is a quality management system, equipment and process in place to ensure that devices being manufactured and sold as NTEP Certified devices do indeed have the capability of meeting the influence factor requirements of HB 44. The methods used to achieve this will be varied from company to company. They may even vary within a company. VCAP is not meant to be an obstacle for how a company chooses to best operate.

Question: Will there be follow up visits by the auditor?

Answer: Yes currently that is proposed to be every five years

Question: What happens in between?

Answer: The current proposal is a self-audit conducted by the CC holder. This audit would be based on an NTEP approved sampling plan based on a recognized standard such as ANSI. The CC holder would keep records of the various device audits and any required corrective action that took place. The auditor at the follow up audit would review these records.

Question: Will NTEP have a standard for the auditor to use? Who will actually conduct this audit?

Answer: The answer to this question still lies in the work to be completed by the work group. Different options have been discussed regarding the details of exactly how this will be accomplished. NTEP could possibly complete work on it own standard for VCAP and identify specific auditors that would be certified to complete the audits. There are also several certification programs that are currently operating that are specific to weighing devices meeting the influence factor requirements. One or all of these certification programs could be recognized by NCWM as acceptable. I suggest we let the work group do its job and then we all can discuss the results of that group when they become available.

This topic received many comments at the Annual meeting. I think that it is clear that there is general consensus that devices meeting influence factor requirements is an important parameter and must be verified. I will not pretend that I have all of the answers to the remaining questions about the details of this program. But it is my commitment to challenge the work group to come up with a proposal that will be tough, but fair, in dealing with this issue. Once this is proposed, the NCWM Board will be reviewing that proposal and will be seeking additional input from all of you.

If you have any comments or questions regarding Conformity Assessment, suggestions or how to improve the items discussed or any other information, the NCWM Board and I would be very anxious to hear from you.

Appendix. Subset of draft proposal discussed at the Annual meeting as it relates to VCAP.

For weighing devices that are subject to influence factors, NTEP will require an initial on-site audit of the manufacturers' quality system and (on-site) random testing and/or review of a production device(s) by the Registrar to verify that all items listed below are currently implemented and functioning to verify compliance to the appropriate sections of NIST Handbook 44:

Weighing Devices:

1. Load Cell (T.N.8.)
2. Indicating elements (T.N.8.)
3. Weighing/Load Receiving elements with non-NTEP load cells (T.N.8.)
4. Complete Scales (T.N.8.)
5. AWS (T.7.)
6. Belt-Conveyor (T.3)
7. ABWS (T.7.)

Required Items to verify

a. **The Manufacturer has: (*notes in parentheses are original item numbers from Newsletter article.)***

   1. (Item 2) A documented Quality Management system governing the design and manufacture of the device.
   2. (Item 6) Appropriate production and testing facilities and equipment
   3. (Item 5) Identified the applicable Metrologically Significant Components (MSC's) of the device.
   4. (Item 4) Appropriate statistical methods implemented to ensure that the process is in control
   5. (Item 3) An appropriate sampling plan, and acceptance criteria in place and operating
   6. (Item 7) Required operator's manuals and calibration procedures for all appropriate production and testing equipment
   7. (New) A Nonconforming Material system to control nonconforming / non- compliant devices and components (either manufactured or purchased).
   8. (Item 9) Adequate control over Subcontractors and sub-tier suppliers
   9. (Item 8) Appropriate Corrective Action system to deal with nonconforming / non-compliant devices
   10. (New) An Engineering Change system to control engineering/design changes affecting any MSC's.
   11. (New) A Document and Data Control (including software and firmware) system to control changes affecting and MSC's.
   12. (New) A Production Control system to control changes affecting any MSC's.
   13. (New) An Identification and Traceability system (including serialization and lot/batch control as applicable) applied, as a minimum, to MSC's.
   14. (Item 1) Documentation that personnel have been properly trained.

b. If the manufacturer contracts with an outside laboratory to conduct the Influence Factor testing, that laboratory will be subject to all applicable Conformity Assessment Program requirements.

c. A subsequent audit report provided by the Registrar, at least every five years, verifying an on-site visit to the manufacturing facility to review the statistical quality assurance and production records for all affected certified devices, and random testing or review of a production device in the manufacturing facility. (Note question: Should we still have some information submitted in the off years between the five years?)

Appendix C

Report on the Activities of the International Organization of Legal Metrology (OIML) and Regional Legal Metrology Organizations

International Legal Metrology Group
Weights and Measures Division, NIST

The International Legal Metrology Group (ILMG) in the Weights and Measures Division (WMD) of the National Institute of Standards and Technology (NIST) is responsible for coordinating U.S. participation in OIML and other international legal metrology organizations. Learn more about OIML at the ILMG website at *http://ts.nist.gov/oiml* or at the OIML website at http://www.oiml.org on the Internet. Dr. Charles Ehrlich, Group Leader of the ILMG, can be contacted at charles.ehrlich@nist.gov or at 301-975-4834 or by fax at 301- 975-5414.

Table of Contents

I. Report on the Activities of the OIML Technical Committees

This section provides a report on the status of work in OIML Technical Committees (TCs) and Technical Subcommittees (SCs) of specific interest to members of the NCWM. Also included are reports on recent activities of those groups and schedules of future activities of Secretariats, the U.S. National Working Groups (NWGs), and the International Working Groups (IWGs) of committees and subcommittees.

TC 3 Metrological Control (United States of America)
A joint working group of the OIML, the International Bureau of Weights and Measures (BIPM), and the International Laboratory Accreditation Cooperation (ILAC) developed the revision of OIML D1 "Elements for a Law on Metrology". The document is now in its third committee draft, and is being reviewed by members of TC3 and the Laws and Regulations Committee. This revision of D1 presents the various elements that should be considered when preparing laws related to metrology. This document gives advice on general laws covering all the aspects of metrology, as well as specific laws related to some distinct aspect of metrology, such as legal units and traceability. It can also be used to evaluate provisions related to metrology in more general laws such as those on consumer protection and conformity assessment. When completed, the document will be a tool that individuals can use in preparing such laws. They can select appropriate elements and adapt them into their legislation. Please contact Kathy Dresser at 301-975-3289 or at kathryn.dresser@nist.gov if you would like to obtain a copy of the 3rd draft revision of D1 or to participate in this project, which is planned for final approval in 2004.

TC3/SC1 "Pattern Approval and Evaluation" (United States)
The International Documents dealing with metrological control of measuring instruments using the processes of type approval and verification have not been revised in over 15 years. The existing OIML documents are D19 "Pattern evaluation and pattern approval" and D20 "Initial and subsequent verification of measuring instruments and processes." A first US proposal has been circulated for a combined revision of OIML D19 and D20 into a single document "Principles of metrological control of measuring instruments: type approval and verification."

The existing documents are out of date since they do not include developments of the last fifteen years, such as the OIML certificate system, D27 "Initial verification of measuring instruments utilizing the manufacturer's quality management system," and the "Framework for a mutual acceptance arrangement (MAA) on OIML type evaluations." Consideration needs to be given to the appropriate conformity assessment options developed by the ISO Council Committee on Conformity Assessment (ISO CASCO). This includes quality systems, product certification, and

accreditation. Consideration needs to be given as well to information technology and statistical methods to increase or decrease verification intervals based upon proven instrument performance. For more information on this activity, contact Dr. Ambler Thompson at 301-975-2333 or at ambler@nist.gov.

TC 5/SC 1 Electronic Instruments (Netherlands)
A meeting was held in the Netherlands in October 2002 to discuss comments received on the 2nd committee draft (2CD) of a revision of D11 "General Requirements for Electronic Measuring Instruments." There were a number of new proposals for tests to be added to D11. Based on meeting discussions and other comments received on the 2CD, a 3CD was circulated by the Secretariat in May 2003. The US voted yes and provided comments on the 3CD in September 2003. This is an especially important document in the OIML system because its testing requirements will become general guidance for all OIML recommendations for electronic measuring instruments. For more information on this activity, contact Dr. Ambler Thompson at 301-975-2333 or at ambler@nist.gov.

TC 8/SC 3 "Measuring Instruments for Liquids other than Water." (Germany) and
TC 8/SC 4 "Dynamic Mass Measurements (Liquids other than Water)" (United States)
OIML R117 "Measuring Instruments for Liquids other than Water" is undergoing an extensive revision -- incorporating new instrument technologies and merging the document with OIML recommendations R86 "Drum Meters" and R105 "Mass Flowmeters." This is a high priority project for OIML, and ILMG is working with the U.S. National Working Group on flowmeters, Germany, and the Netherlands (convener of the work group tasked with revising R117) on this effort. Meetings of the U.S. National Working Group on flowmeters were held during the NCWM Interim Meeting in January 2003 and the NCWM Annual Meeting in July 2003. Measurement Canada has been a strong contributor to this effort. An aggressive timetable for TC8/SC3 and SC4 to complete this major project is ongoing.

An extremely productive joint meeting of OIML TC8/SC3 and SC4 was held October 6-9, 2003 in Paris, France. The meeting was very well attended by 45 participants, including official representatives from 17 countries. Several representatives of major U.S. manufacturers of these systems actively participated in the meeting. These technical experts provided a depth of experience and technical expertise that proved highly valuable during the meeting. Working from the first committee draft of R117 (1CD, Aug 2003), participants at the 4-day Paris meeting successfully completed a hefty and detailed agenda designed to resolve several key issues on the document's revision. Some of these key issues included: conversion devices, electronic sealing, significant faults, endurance testing, and required documentation. Based largely on the consensus decisions reached by meeting participants, the second committee draft (2CD) of R117 is expected to be ready for review in December 2003. If you have questions or would like to become more involved with this effort, please contact Mr. Ralph Richter at ralph.richter@nist.gov or 301-975-4025.

TC8/SC5 "Water Meters" (United Kingdom)
The amended R49-1 "Water Meters Intended for the Metering of Cold Potable Water: Metrological Requirements" was republished and placed on the OIML web site in April 2002. Amended versions of both R49-2 "Test Methods" and R49-3 "Test Report Format" were approved for publication at the November 2003 CIML meeting in Kyoto, Japan.

TC8/SC7 "Gas Metering" (Belgium and France)
An IWG meeting was held in Brussels in March 2001 to discuss a 2nd CD draft of OIML Recommendation "Measuring Systems for Gaseous Fuel" to include natural and compressed natural gas. The meeting focused on discussion of comments on the 2nd CD draft Recommendation. A second meeting of the IWG focused on a 2nd CD Recommendation "Measuring Systems for Compressed Natural Gas (CNG) for Vehicles" and annexes covering performance tests for electronic devices and basic test procedures. The Secretariat circulated a 3rd CD "Measuring Systems for Compressed Natural Gas (CNG) for Vehicles" for comment and vote. In April 2003, the United States cast a negative ballot because the testing requirements were unrealistic. Please contact Wayne Stiefel at 301-975-4011 or at stiefel@nist.gov if you would like to obtain a copy of the 3rd CD or participate in this project.

TC 8/SC 8 "Gas Meters" (Netherlands)
The Secretariat sent the members of the committee a letter with the results of a questionnaire asking for comments to guide the initiation of a work program to revise R6 "General provisions for gas volume meters," R31 "Diaphragm Gas Meters", and R32 "Rotary Piston Gas Meters and Turbine Gas Meters." A small majority of members voted to produce one new recommendation for gas meters that will replace R6, R31, and R32. The Secretariat reported that they would develop an initial draft. The new document, according to the Secretariat, may consist of a general chapter mainly consisting of R6 and those aspects in common with R31 and R32 and separate chapters on household and industrial gas meters. The U.S. NWG provided comments and will participate in the development of the new Recommendation. Please contact Wayne Stiefel at 301-975-4011 or at stiefel@nist.gov if you would like to participate in this project.

TC 9/SC 1 "Nonautomatic Weighing Instruments" (Germany and France)
In May of 2002, Germany and France, the co-secretariats of OIML TC 9/SC 1 "Non-automatic Weighing Instruments" (NAWI), announced that they had initiated the first review of OIML Recommendation 76 "Non-automatic Weighing Instruments" since 1994. This review cycle is of major importance to U.S. interests because R76 serves as the foundation for a majority of the laws and regulations that governs weighing instruments around the world. This review is significant for U.S. weighing instrument manufacturers because the international harmonization of requirements will eliminate technical barriers to trade and reduce the delays and the cost of getting new weighing instruments into the global marketplace. It is also important for legal metrology officials since it is taking place when the NCWM is considering entering into Mutual Acceptance Arrangements for type evaluations with other countries (e.g., Germany). This effort supports one of the Conference's long-range strategies that is to "work toward the harmonization of U.S. (e.g., NIST Handbook 44 "Specifications, Tolerances, and Other Technical Requirements for Weighing and Measuring Devices") and international standards." The review process for R76 began with the Co-Secretariats requesting comments from Member States using a questionnaire. The US is expecting the first working draft of the revised R76 in November or December 2003. If you would like to participate in this effort, please contact Steve Cook at 301-975-4003 or steven.cook@nist.gov.

TC 9/SC 2 "Automatic Weighing Instruments" (United Kingdom)
In July of 2003, the US voted "no" on a third committee draft of Recommendation "Automatic Instruments for Weighing Road Vehicles in Motion - Part B - Axle Loads" that was prepared by the OIML Secretariat in the United Kingdom. Several technical and clarification items were forwarded to the secretariat as justification for this negative vote. If you would like to receive a copy of the latest draft of this document or participate in this work please contact Richard Harshman at 301-975-8107 or harshman@nist.gov.

TC17/SC1 "Humidity" (China)
In February 2001, the 1st Committee Draft Revision of OIML R59 "Moisture Meters for Cereal Grains and Oilseeds" was received from the TC17/SC1 Secretariat, the Peoples Republic of China. The current edition of R59 was developed in the 1980s and includes technical and metrological requirements for both automatic and manual meters. A U.S. National Working Group reviewed the draft revision of R59 and sent comments to the Secretariat in the spring of 2001. Because of substantial problems with this draft, the Secretariat asked the United States to prepare a new OIML draft based on the National Conference on Weights and Measures National Type Evaluation Program (NTEP) requirements. A working draft of the Recommendation was prepared based upon requirements for moisture meters in Handbook 44 and Publication 14. After preparation by the United States, this working draft was distributed by China to the IWG in February 2003 for comment. Based on comments received on the working draft, a first committee draft was distributed to the IWG in May 2003. Both drafts were also distributed to the U.S. National Working Group, which for the most part is a subset of the NTEP Grain Sector. In October 2003, China hosted a meeting of the TC17/SC1 subcommittee in Beijing to review and discuss this revised document. Please contact Diane Lee at 301-975-4405 or at diane.lee@nist.gov if you would like to participate in this working group.

II. Mutual Acceptance Arrangement (MAA) on OIML Type Evaluations

The MAA document and its associated document "Checklists for issuing authorities and testing laboratories carrying out OIML type evaluations" were both adopted at the 38th CIML meeting in November 2003 in Kyoto, Japan, after presentations given by the BIML Director and Dr. Charles Ehrlich, the Secretariat of TC3. The CIML agreed to set up a working group in order to address the financial aspects of the implementation of the MAA and to come up with financial regulations for this MAA before the 2004 CIML Meeting. The CIML also instructed the BIML and the TC3 Secretariat to prepare for the implementation of the MAA as soon as possible.

III. Report on the 38th Meeting of the International Committee of Legal Metrology (CIML)

Representatives from 49 of the 60 member nations participated in the 38th Annual Meeting of CIML from November 5-8, 2003, in Kyoto, Japan. The CIML President welcomed two new member countries, New Zealand and Vietnam. Meetings of the OIML Presidential and Development Councils were also held. Dr. C. Ehrlich is the CIML Member for the United States.

The CIML approved the following draft Recommendations and Documents in Kyoto:

- Revision of R 48
  Tungsten ribbon lamps for calibration of radiation thermometers;

- Amended version of R 49-2
  Water meters intended for metering cold potable water. Part 2: Test methods;

- Draft Recommendation R 49-3
  Water meters intended for metering cold potable water. Part 3: Test report format;

- Revision of R 52
  Hexagonal weights, ordinary accuracy class from 100 g to 50 kg;

- Revision of R 61-1
  Automatic gravimetric filling instruments, Part 1: Metrological and technical requirements - Tests;

- Draft Revision of R 61-2
  Automatic gravimetric filling instruments. Part 2: Test report format;

- Revision of R 87
  Quantity of products in prepackages;

- Draft amendment to OIML R 99/ISO 3930
  Instruments for measuring vehicle exhaust emissions;

- Draft Recommendation R 134
  Automatic instruments for weighing road vehicles in motion - Test Report Format; and

- New Recommendation (R 135)
  Spectrophotometers for medical laboratories.

Budget
The BIML Director gave a presentation on a preliminary proposal for the 2005-2008 OIML budget. The Committee approved the guidelines set out in this document and instructed the BIML Director to prepare a proposal for the 2004 Conference, highlighting the distinction between (1) the normal budget, financed by Member State Contributions, and other usual income of the Organization; and (2) the optional, additional budget, corresponding to the implementation of the MAA and changes in the way in which publications will be distributed, and whose charges and income shall be specific. The Committee also noted information given by the BIML Director concerning the revision of the OIML Financial Regulations. The Committee instructed the Bureau to complete this Draft Revision and to submit it to Member States in time for approval at the 39th CIML Meeting and 12th OIML Conference in 2004.

Work of the TCs/SCs
Concerning the OIML technical activities, the CIML expressed its satisfaction with the increased volume of work accomplished during the last 12 months (compared with the previous one-year period). The CIML requested OIML TCs and SCs continue to accelerate their work, especially in the fields listed as high priority and priority projects. The Committee discussed several proposals included in the document entitled "Acceleration of OIML technical work," instructing members to start implementing the proposed actions. The Committee also instructed the BIML to regularly report back at CIML Meetings on the measures taken and results achieved.

The Committee approved the project as proposed by TC 18 on *Ophthalmic instruments - Impression and applanation tonometer.*

The Committee noted a proposal submitted by France to develop 'interpretation documents' pertaining to the accreditation of legal metrology Issuing Authorities and Testing Laboratories. Noting an agreement between the TC3/SC5 Secretariat (U.S.) and the BIML, the Committee instructed TC3/SC5 to set up a Working Group (convened jointly by France and the BIML) to develop the first drafts of these documents.

The Committee also noted information provided by the BIML on the generally unsatisfactory situation of CIML postal voting in 2003, and requested its Members (especially those who are late in voting) to comply more regularly with fulfilling their duties, thus contributing to the timely approval of drafts submitted.

OIML Certificate System
The CIML decided that the following Recommendations would be applicable within the OIML Certificate System when published:

- Revision of R 48, *Tungsten ribbon lamps for calibration of radiation thermometers*;

- New Recommendation - R 135, *Spectrophotometers for medical laboratories*.

The CIML noted several proposed actions for implementing the revised P1 "OIML Certificate System for Measuring Instruments:"

- The responsible TCs/SCs should include new provisions for modules and families of measuring instruments (as far as the definition of families, identification of modules and/or families together with their metrological requirements, test methods, and test report forms are concerned) when developing new or revising existing Recommendations intended for application within the OIML Certificate System, in order that Certificates may be issued accordingly;

- The TCs/SCs concerned should accelerate the development of horizontal type OIML Documents (e.g. on software, uncertainty, etc.) to be implemented when drawing up new and revised Recommendations;

- The BIML should assist TCs/SCs and Issuing Authorities in the implementation (realization of new and additional tasks) of the revised P1; and

- CIML Members and the BIML should pursue further general actions in promoting the OIML Certificate System at national, international and regional levels, and keep international and regional organizations in liaison with the OIML informed of the advantages of the OIML Certificate System with special regard to its new features.

The Committee instructed the BIML to carry out inquiries among OIML members and among manufacturers and applicants who already possessed OIML certificates as to their experience in the voluntary acceptance and use of OIML certificates for national or regional type approvals, as well as to their views on the functioning of the OIML Certificate System with a special view to the new provisions of P1. The outcome of these inquiries shall be included in the report on the OIML Certificate System to be presented in 2004.

Study on the benefits of legal metrology
Mr. John Birch gave a presentation on his report *The Benefits of Legal Metrology for the Economy and Society*. The Committee expressed its great appreciation of this report and instructed the BIML to distribute it as an expert report. A summary report compiled by Mr. Birch would also be published in the OIML Bulletin. The Committee instructed the CIML President and the BIML to consider any complementary actions or studies, which would be helpful in raising the awareness of metrology and legal metrology.

Liaisons with international and regional institutions
The CIML President gave a report on the good cooperation OIML enjoys with the Metre Convention (BIPM/CIPM) and with ILAC.

The Committee approved a policy paper on OIML liaisons with other organizations.

The Committee noted a progress report given by the BIML Director on a paper formalizing OIML relations and cooperation with Regional Legal Metrology Organizations (RLMOs); this paper is being submitted for comments to the RLMOs. The Committee instructed the BIML to continue progress with this paper so as to establish a formal framework for OIML cooperation with the RLMOs.

Upcoming OIML Meetings

The next meeting of the OIML Presidential Council will be held in March 2004 in Paris. The 2004 CIML meeting will be held in conjunction with the next quadrennial OIML Conference in Berlin, Germany, from October 25 – 29, 2004. The 2005 CIML meeting will be held in Paris to coincide with the 50th Anniversary of the establishment of OIML.

Appendix D

Harmonization with OIML: What It Means and How It Will Happen

Ross Andersen, NTEP Chair
Version 1: November 19, 2003

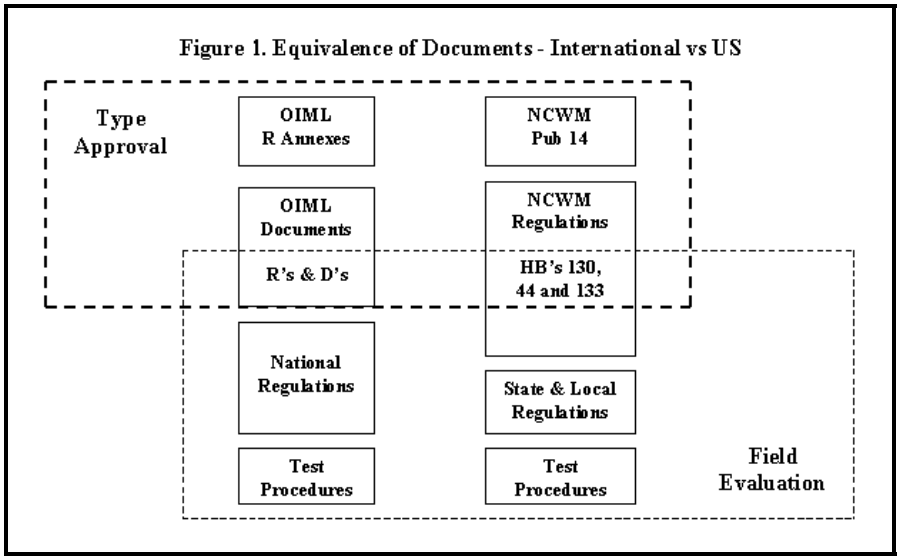
The NCWM Board recognized the importance of harmonization with OIML in its strategic plan. Several initiatives are already underway to move the NCWM in that direction, so this is now much more than a plan. This article is intended to provide the NCWM membership with a simple roadmap of what is happening and who will have responsibilities to make it a reality.

Perhaps the first issue that must be addressed is to clarify what "harmonization" is. In simple terms, harmonization is making requirements in U.S. and OIML documents consistent to the extent practical, in order to reduce or remove technical barriers to trade. The United States, as a signatory of the OIML Convention, has obligations to consider OIML recommendations whenever amending its technical regulations and use the OIML standards except where there is compelling reason to do otherwise. However, the U.S. system and its approach to regulation are somewhat different from other countries and this adds to the difficulty.

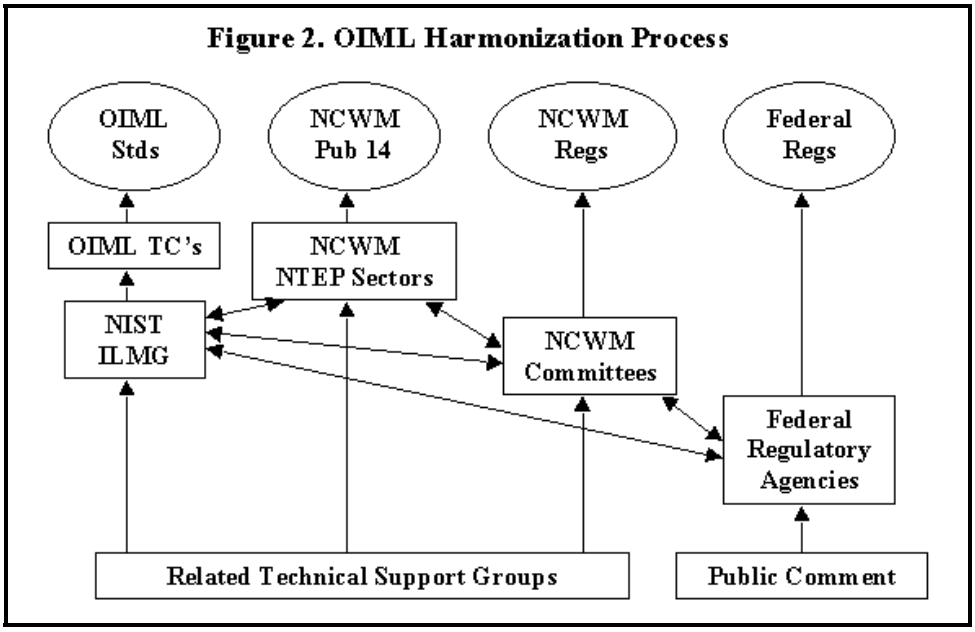
The United States does not have a single mechanism to harmonize with OIML at the federal level as other countries do. Weights and measures in the United States is primarily a state and local function. The NCWM was conceived to get the states to buy-in and work together in order to have a uniform system of regulations. The NCWM, as the primary U.S. standards setting organization in the legal metrology field, thus bears the responsibility of following through to meet our treaty obligations.

The U.S. approach to legal metrology is primarily directed to field verification. In its introduction, Handbook 44 states that the purpose of the requirements is to "eliminate from use" devices that are inaccurate, or false, or facilitate the perpetration of fraud. In contrast, the OIML recommendations are aimed primarily at the type approval process. OIML creates recommendations to provide a uniform means of evaluating the design and performance of weighing and measuring instruments.

The differences in approach produce differences in the technical documents that further add to the difficulty in harmonization. Other nations use the OIML Recommendations in their type approval programs. They use the test procedures and report forms in the annexes. For the most part, field verification and field test procedures are not part of the OIML technical standards, but are developed separately in different countries as national legislation that is supplemented with specific test procedures based on the Recommendations. (See Figure 1.) The U.S. documents do essentially the same things, but not with direct correlation to the OIML documents. When we harmonize, it will not necessarily mean the adding or amending a paragraph in Handbook 44.



With these differences in mind, the Board has set some broad objectives to move ahead in a three-pronged attack. This involves the NIST International Legal Metrology Group (ILMG) in the Weights and Measures Division (WMD), the NCWM standing committees, and the NTEP sectors, each working in its particular area of responsibility and using appropriate procedures to ensure due process. The NIST ILMG or other WMD staff will take the U.S. positions to OIML technical committees or subcommittees in those areas where we think we have a better standard or the OIML standard could be improved. The NCWM standing committees will consider proposals to change the U.S. technical standards to remove barriers to trade. The NTEP sectors will consider amendments to Publication 14. In addition, where federal agencies have regulations preempting the states, these agencies will have similar obligations to harmonize their requirements with OIML. The NCWM is essentially a public participant in these federal regulatory activities. I included them in Figure 2 below only for reference and not as part of the NCWM strategic plan. Hopefully the NCWM will be an active participant in those areas like metric only labeling.



The work of the three groups needs to be coordinated and there will be considerable need for education as we move forward with the harmonization process as indicated in Figure 2. The process can originate at any level in the system, from individuals to the Committees charged with the responsibility for the codes. It is important to realize that OIML has a schedule of revision of its documents that is largely outside of U.S. control, and so the ILMG/WMD staff will accordingly be bringing matters to the attention of NCWM when they arise in OIML. All of the involved parties need to work together to take the necessary steps to bring about change. This includes:

- Identifying technical barriers to trade (i.e., differences between OIML and U.S. requirements);
- Fostering discussion on where to consider changes (in OIML recommendations, U.S. standards, or Pub 14);
- Setting priorities on which issues to tackle first;
- Educating affected parties of the needs/benefits of harmonization; and
- Promoting the necessary action at the appropriate level with due process.

Changes proposed to OIML standards will go through the NIST ILMG/WMD to the OIML technical committees and subcommittees. The United States has been successful in getting OIML to accept some of our ideas. When we originally proposed the mix and match concept, OIML rejected it. However, today they recognize what they call modules and have a system of apportioning the errors to modules that may be superior to ours.

We may want to make changes to NCWM standards in some areas. For example, in the area of device terminology, we have differences that could easily be changed. Automatic zero setting mechanisms could easily be renamed to the OIML term “zero tracking” with little fanfare. At the other extreme, changing all our Class III L vehicle scale requirements to

meet OIML Class III might be quite hard to sell to our manufacturers and users. Any changes proposed to our technical standards would go through the NCWM standing committees to ensure due process is observed.

In the third area, i.e., changes to Pub 14, any proposals for change will go through the NTEP sectors and the NTEP Committee. These changes may be mostly transparent to the end user and the field inspector. For example, our test procedures for load cells are fairly close to the OIML. Except for some specific tests for humidity and electrical disturbances, we could adopt the OIML procedures today. We must examine the nature of the link between NTEP and the technical regulations in Handbook 44. Each NTEP certificate includes a statement that the device has demonstrated ability to comply with the Handbook. Obviously we can't use test methods in NTEP that evaluate to a lower standard. On the other hand, can we test using a stricter standard? For example, Class III scales in the Handbook have a fourth tolerance step, not present in OIML. If the scales and load cells were evaluated per OIML tests with only three tolerance steps, it may easily satisfy compliance with the extra step. In many cases the OIML standards are stricter than U.S. standards. Using OIML test procedures and standards in NTEP would serve to harmonize, would produce better devices, and would still be almost transparent to the user and the field official.

OIML spreads out the technical work and has been successful in using electronic means to reduce need for meetings. They have a system of about 50 technical committees and subcommittees, 20 of which deal with weights and measures law, trade devices and prepackages, while we have only our L&R and S&T Committees and our sectors. Consider also that their Technical Committees don't have to deal with application or field testing issues that often dominate our agendas (i.e., 17 of 24 voting items on 2003 S&T agenda were field related). Whether it is a national working group, a regional association, or an NTEP sector, we in the United States need to ensure that we get the experts involved as we review and update our technical standards.

In all of these harmonization activities, there is another important support layer. Regional and state W&M associations, industry associations and individual companies, state and local W&M jurisdictions and officials, technical advisors from NIST and Measurement Canada, and other interested parties all contribute to the work of the NCWM. Most of these are already actively involved in NCWM standards setting for application and field enforcement issues. I fear that these groups may not be fully equipped to deal with device specifications and performance standards. In some respects the NTEP sectors have been asked to fill that role. I believe that the U.S. National Working Groups (U.S.NWGs) need to become the center of our technical work on device specifications and performance standards. I believe the U.S. NWGs need to be thought of as part of the NCWM support structure on a par with our regional and industry associations. To this end, it is vital that knowledgeable regulatory officials from the federal regulatory agencies and the state and local jurisdictions get involved in these activities. To get involved, contact the NIST ILMG. You can participate at any level from observer to full member.

I have heard it expressed that extensive adoption of OIML standards may make the work of the S&T Committee unnecessary. I have come to believe that adoption of OIML standards will only make that work more important. In between updates of the OIML standards there are always new technical issues to face that impact design and performance. In addition, OIML technical regulations must be supplemented by national legislation in the areas of application and verification. Change is inevitable and we will continue to adjust our standards and our regulatory system to adapt.

I can report a major success that began with a NIST-contracted comparison of scale requirements in Handbook 44 and OIML R76 by John Elengo. That comparison served as the focus of a meeting of the weighing instruments U.S.NWG in August. The group provided the NIST ILMG with a number of items to take to OIML committees working on R76. It also identified and prioritized some efforts to change U.S. requirements in both Handbook 44 and Pub 14. As a result, this year and for years to come, I expect to see harmonization issues appear on our S&T Committee and Weighing Sector agendas. I also expect to see U.S. ideas showing up in OIML documents. NIST has already contracted for a second such comparison on liquid measuring devices. As we work on these items together, it is my hope that we continue to move forward in removing barriers to trade in a process that will help make our regulatory system stronger and make the United States stronger in the world market. I am confident that as we learn more about the OIML standards we will see more benefit in using them.